106TH CONGRESS 2D SESSION

S. 3108

To amend the Federal Insecticide, Fungicide, and Rodenticide Act to permit a State to register a Canadian pesticide for distribution and use within that State.

IN THE SENATE OF THE UNITED STATES

September 26 (legislative day, September 22), 2000

Mr. Dorgan introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

- To amend the Federal Insecticide, Fungicide, and Rodenticide Act to permit a State to register a Canadian pesticide for distribution and use within that State.
 - 1 Be it enacted by the Senate and House of Representa-
 - 2 tives of the United States of America in Congress assembled,
 - 3 SECTION 1. REGISTRATION OF CANADIAN PESTICIDES BY
 - 4 STATES.
 - 5 (a) In General.—Section 24 of the Federal Insecti-
 - 6 cide, Fungicide, and Rodenticide Act (7 U.S.C. 136v) is
 - 7 amended by adding at the end the following:
- 8 "(d) Registration of Canadian Pesticides by
- 9 States.—

1	"(1) Definitions.—In this subsection:
2	"(A) CANADIAN PESTICIDE.—The term
3	'Canadian pesticide' means a pesticide that—
4	"(i) is registered for use as a pesticide
5	in Canada;
6	"(ii) is identical or substantially simi-
7	lar in its composition to a comparable do-
8	mestic pesticide registered under section 3;
9	and
10	"(iii) is registered in Canada by the
11	registrant of the comparable domestic pes-
12	ticide or by an affiliated entity of the reg-
13	istrant.
14	"(B) Comparable domestic pes-
15	TICIDE.—The term 'comparable domestic pes-
16	ticide' means a pesticide—
17	"(i) that is registered under section 3;
18	"(ii) the registration of which is not
19	under suspension;
20	"(iii) that is not subject to—
21	"(I) a notice of intent to cancel
22	or suspend under any provision of this
23	Act;
24	"(II) a notice for voluntary can-
25	cellation under section 6(f); or

1	"(III) an enforcement action
2	under any provision of this Act;
3	"(iv) that is used as the basis for
4	comparison for the determinations required
5	under paragraph (4);
6	"(v) that is registered for use on each
7	site of application for which registration is
8	sought under this subsection;
9	"(vi) for which no use is the subject
10	of a pending interim administrative review
11	under section $3(c)(8)$;
12	"(vii) that is not subject to any limita-
13	tion on production or sale agreed to by the
14	Administrator and the registrant or im-
15	posed by the Administrator for risk mitiga-
16	tion purposes; and
17	"(viii) that is not classified as a re-
18	stricted use pesticide under section 3(d).
19	"(2) Authority to register canadian pes-
20	TICIDES.—
21	"(A) In general.—A State may register
22	a Canadian pesticide for distribution and use in
23	the State if the registration—
24	"(i) complies with this subsection;
25	"(ii) is consistent with this Act; and

1	"(iii) has not previously been dis-
2	approved by the Administrator.
3	"(B) Production of Another Pes-
4	TICIDE.—A pesticide registered under this sub-
5	section shall not be used to produce a pesticide
6	registered under section 3 or subsection (c).
7	"(C) Effect of registration.—A reg-
8	istration of a Canadian pesticide by a State
9	under this subsection—
10	"(i) shall be deemed to be a registra-
11	tion under section 3 for all purposes of this
12	Act; and
13	"(ii) shall authorize distribution and
14	use only within that State.
15	"(D) Registrant.—
16	"(i) In general.—A State may reg-
17	ister a Canadian pesticide under this sub-
18	section on its own motion or on application
19	of any person.
20	"(ii) State or applicant as reg-
21	ISTRANT.—
22	"(I) State.—If a State registers
23	a Canadian pesticide under this sub-
24	section on its own motion, the State
25	shall be considered to be the reg-

1	istrant of the Canadian pesticide for
2	all purposes of this Act.
3	"(II) Applicant.—If a State
4	registers a Canadian pesticide under
5	this subsection on application of any
6	person, the person shall be considered
7	to be the registrant of the Canadian
8	pesticide for all purposes of this Act.
9	"(3) Requirements for registration
10	SOUGHT BY PERSON.—A person seeking registration
11	by a State of a Canadian pesticide in a State under
12	this subsection shall—
13	"(A) demonstrate to the State that the Ca-
14	nadian pesticide is identical or substantially
15	similar in its composition to a comparable do-
16	mestic pesticide; and
17	"(B) submit to the State a copy of—
18	"(i) the label approved by the Pes-
19	ticide Management Regulatory Agency for
20	the Canadian pesticide; and
21	"(ii) the label approved by the Admin-
22	istrator for the comparable domestic pes-
23	ticide.

1	"(4) State requirements for registra-
2	TION.—A State may register a Canadian pesticide
3	under this subsection if the State—
4	"(A) obtains the confidential statement of
5	formula for the Canadian pesticide;
6	"(B) determines that the Canadian pes-
7	ticide is identical or substantially similar in
8	composition to a comparable domestic pesticide;
9	"(C) for each food or feed use authorized
10	by the registration—
11	"(i) determines that there exists an
12	adequate tolerance or exemption under the
13	Federal Food, Drug, and Cosmetic Act (21
14	U.S.C. 301 et seq.) that permits the resi-
15	dues of the pesticide on the food or feed;
16	and
17	"(ii) identifies the tolerances or ex-
18	emptions in the notification submitted
19	under subparagraph (E);
20	"(D) obtains a label approved by the Ad-
21	ministrator that—
22	"(i)(I) includes all statements, other
23	than the establishment number, from the
24	approved labeling of the comparable do-

1	mestic pesticide that are relevant to the
2	uses registered by the State; and
3	"(II) excludes all labeling statements
4	relating to uses that are not registered by
5	the State;
6	"(ii) identifies the State in which the
7	product may be used;
8	"(iii) prohibits sale and use outside
9	the State identified under clause (ii);
10	"(iv) includes a statement indicating
11	that it is unlawful to use the Canadian
12	pesticide in the State in a manner that is
13	inconsistent with the labeling approved by
14	the Administrator under this subsection;
15	and
16	"(v) identifies the establishment num-
17	ber of the establishment in which the label-
18	ing approved by the Administrator will be
19	affixed to each container of the Canadian
20	pesticide; and
21	"(E) not later than 10 business days after
22	the issuance by the State of the registration,
23	submit to the Administrator a written notifica-
24	tion of the action of the State that includes—

1	"(i) a description of the determination
2	made under this paragraph;
3	"(ii) a statement of the effective date
4	of the registration;
5	"(iii) a confidential statement of the
6	formula of the registered pesticide; and
7	"(iv) a final printed copy of the label-
8	ing approved by the Administrator.
9	"(5) Disapproval of registration by Ad-
10	MINISTRATOR.—
11	"(A) In General.—The Administrator
12	may disapprove the registration of a Canadian
13	pesticide by a State under this subsection if the
14	Administrator determines that the registration
15	of the Canadian pesticide by the State—
16	"(i) does not comply with this sub-
17	section or the Federal Food, Drug, and
18	Cosmetic Act (21 U.S.C. 301 et seq.); or
19	"(ii) is inconsistent with this Act.
20	"(B) Effective Period.—If the Admin-
21	istrator disapproves a registration by a State
22	under this subsection by the date that is 90
23	days after the date on which the State issues
24	the registration, the registration shall be inef-
25	fective after the 90th day.

1	"(6) Labeling of Canadian Pesticides.—
2	"(A) In general.—Each container con-
3	taining a Canadian pesticide registered by a
4	State shall bear the label that is approved by
5	the Administrator under this subsection.
6	"(B) DISPLAY OF LABEL.—The label shall
7	be securely attached to the container and shall
8	be the only label visible on the container.
9	"(C) ORIGINAL CANADIAN LABEL.—The
10	original Canadian label on the container shall
11	be preserved underneath the label approved by
12	the Administrator.
13	"(D) Preparation and use of la-
14	BELS.—After a Canadian pesticide is registered
15	under this subsection, the registrant shall—
16	"(i) prepare labels approved by the
17	Administrator for the Canadian pesticide;
18	and
19	"(ii) conduct or supervise all labeling
20	of the Canadian pesticide with the ap-
21	proved labeling.
22	"(E) REGISTERED ESTABLISHMENTS.—
23	Labeling of a Canadian pesticide under this
24	subsection shall be conducted at an establish-

1	ment registered by the registrant under section
2	7.
3	"(F) ESTABLISHMENT REPORTING RE-
4	QUIREMENTS.—An establishment registered for
5	the sole purpose of labeling under this para-
6	graph shall be exempt from the reporting re-
7	quirements of section 7(c).
8	"(7) Revocation.—
9	"(A) In General.—After the registration
10	of a Canadian pesticide, if the Administrator
11	finds that the Canadian pesticide is not iden-
12	tical or substantially similar in composition to
13	a comparable domestic pesticide, the Adminis-
14	trator may issue an emergency order revoking
15	the registration of the Canadian pesticide.
16	"(B) Terms of order.—The order—
17	"(i) shall be effective immediately;
18	"(ii) may prohibit the sale, distribu-
19	tion, and use of the Canadian pesticide;
20	and
21	"(iii) may require the registrant of the
22	Canadian pesticide to purchase and dispose
23	of any unopened product subject to the
24	order.

1	"(C) Request for hearing.—Not later
2	than 10 days after issuance of the order, the
3	registrant of the Canadian pesticide subject to
4	the order may request a hearing on the order.
5	"(D) Final order.—If a hearing is not
6	requested in accordance with subparagraph (C),
7	the order shall become final and shall not be
8	subject to judicial review.
9	"(E) Judicial review.—If a hearing is
10	requested on the order, judicial review may be
11	sought only at the conclusion of the hearing on
12	the order and following the issuance by the Ad-
13	ministrator of a final revocation order.
14	"(F) Procedure.—A final revocation
15	order issued following a hearing shall be review-
16	able in accordance with section 16.
17	"(8) Suspension of state authority to
18	REGISTER CANADIAN PESTICIDES.—
19	"(A) IN GENERAL.—If the Administrator
20	finds that a State that has registered 1 or more
21	Canadian pesticides under this subsection is not
22	capable of exercising adequate controls to en-
23	sure that registration under this subsection is
24	consistent with this subsection, other provisions

of this Act, or the Federal Food, Drug, and

Cosmetic Act (21 U.S.C. 301 et seq.), or has 1 2 failed to exercise adequate controls of 1 or more Canadian pesticides registered under this sub-3 4 section, the Administrator may suspend the authority of the State to register Canadian pes-6 ticides under this subsection until such time as 7 the Administrator determines that the State 8 can and will exercise adequate control of the 9 Canadian pesticides. 10 "(B) NOTICE AND OPPORTUNITY TO RE-11 SPOND.—Before suspending the authority of a 12 State to register a Canadian pesticide, the Ad-13 ministrator shall— 14 "(i) notify the State that the Adminis-15 trator proposes to suspend the authority 16 and the reasons for the proposed suspen-

sion; and

"(ii) before taking final action to suspend authority under this subsection, provide the State an opportunity to respond to the proposal to suspend within 30 calendar days after the State receives notice under clause (i).

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1 "(9) Limits on liability.—No action for 2 monetary damages may be heard in any Federal 3 court against—

- "(A) a State acting as a registering agency under the authority of and consistent with this subsection for injury or damage resulting from the use of a product registered by the State under this subsection; or
- "(B) a registrant for damages resulting from adulteration or compositional alteration of a Canadian pesticide registered under this subsection if the registrant did not have and could not reasonably have obtained knowledge of the adulteration or compositional alteration.
- "(10) DISCLOSURE OF INFORMATION BY ADMINISTRATOR TO THE STATE.—The Administrator
 may disclose to a State that is seeking to register a
 Canadian pesticide in the State information that is
 necessary for the State to make the determinations
 required by paragraph (4) if the State certifies to
 the Administrator that the State can and will maintain the confidentiality of any trade secrets and commercial or financial information provided by the Administrator to the State under this subsection to the
 same extent as is required under section 10.

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1 "(11) Provision of information by reg-2 Istrants of comparable domestic pes-3 Ticides.—

"(A) In GENERAL.—On request by a State, the registrant of a comparable domestic pesticide shall provide to the State that is seeking to register a Canadian pesticide in the State under this subsection information that is necessary for the State to make the determinations required by paragraph (4) if the State certifies to the registrant that the State can and will maintain the confidentiality of any trade secrets and commercial and financial information provided by the registrant to the State under this subsection to the same extent as is required under section 10.

"(B) Penalty for noncompliance.—

"(i) IN GENERAL.—If the registrant of a comparable domestic pesticide fails to provide to the State, not later than 15 days after receipt of a written request by the State, information possessed by or reasonably accessible to the registrant that is necessary to make the determinations required by paragraph (4), the Administrator

1	may assess a penalty against the registrant
2	of the comparable pesticide.
3	"(ii) Amount.—The amount of the
4	penalty shall be equal to the product ob-
5	tained by multiplying—
6	"(I) the difference between the
7	per-acre cost of the application of the
8	comparable domestic pesticide and the
9	application of the Canadian pesticide,
10	as determined by the Administrator;
11	and
12	"(II) the number of acres in the
13	State devoted to the commodity for
14	which the State registration is sought.
15	"(C) Notice and opportunity for
16	HEARING.—No penalty under this paragraph
17	shall be assessed unless the registrant is given
18	notice and opportunity for a hearing in accord-
19	ance with section $14(a)(3)$.
20	"(D) Issues at Hearing.—The only
21	issues for resolution at the hearing shall be—
22	"(i) whether the registrant of the
23	comparable domestic pesticide failed to
24	timely provide to the State the information
25	possessed by or reasonably accessible to

1	the registrant that was necessary to make
2	the determinations required by paragraph
3	(4); and
4	"(ii) the amount of the penalty.
5	"(12) Penalty for disclosure by state.—
6	"(A) IN GENERAL.—The State shall not
7	make public information obtained under para-
8	graph (10) or (11) that is privileged and con-
9	fidential and contains or relates to trade secrets
10	or commercial or financial information.
11	"(B) DISCLOSURE.—Any State employee
12	who willfully discloses information described in
13	subparagraph (A) shall be subject to penalties
14	described in section 10(f).
15	"(13) Data compensation.—A State or per-
16	son registering a Canadian pesticide under this sub-
17	section shall not be liable for compensation for data
18	supporting the registration if the registration of the
19	Canadian pesticide in Canada and the registration of
20	the comparable domestic pesticide are held by the
21	same registrant or by affiliated entities.
22	"(14) FORMULATION CHANGES.—
23	"(A) In general.—The registrant of a
24	comparable domestic pesticide shall notify the
25	Administrator of any change in the formulation

1 of a comparable domestic pesticide or a Cana-2 dian pesticide registered by the registrant or an 3 affiliated entity not later than 30 days before 4 any sale or distribution of the pesticide containing the new formulation. 6 "(B) STATEMENT OF FORMULA.—The reg-7 istrant of the comparable domestic pesticide shall submit, with the notice required under 8 9 subparagraph (A), a confidential statement of the formula for the new formulation if the reg-10 11 istrant has possession of or reasonable access to 12 the information. "(C) Suspension of registration for 13 14 NONCOMPLIANCE.— 15 "(i) In General.—If the registrant 16 fails to provide notice or submit a con-17 fidential statement of formula as required 18 by this paragraph, the Administrator may 19 issue a notice of intent to suspend the reg-20 istration of the comparable domestic pes-21 ticide for a period of not less than 1 year. 22 "(ii) Effective date.—The suspen-

sion shall become final not later than the

end of the 30-day period beginning on the

date of the issuance by the Administrator

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1	of the notice of intent to suspend the reg-
2	istration, unless during the period the reg-
3	istrant requests a hearing.
4	"(iii) Hearing procedure.—If a
5	hearing is requested, the hearing shall be
6	conducted in accordance with section 6(d).
7	"(iv) Issues.—The only issues for
8	resolution at the hearing shall be whether
9	the registrant has failed to provide notice
10	or submit a confidential statement of for-
11	mula as required by this paragraph.".
12	(b) Conforming Amendments.—
13	(1) Section 24(c) of the Federal Insecticide,
14	Fungicide, and Rodenticide Act (7 U.S.C. 136v(c))
15	is amended—
16	(A) in paragraph (1), by inserting "IN
17	GENERAL.—" after "(1)";
18	(B) in paragraph (2), by inserting "DIS-
19	APPROVAL.—" after "(2)";
20	(C) in paragraph (3), by inserting "Con-
21	SISTENCY WITH FEDERAL FOOD, DRUG, AND
22	COSMETIC ACT.—" after "(3)"; and
23	(D) by striking "(4) If the Administrator"
24	and inserting the following:

- "(4) Suspension of authority to register 1 2 PESTICIDES.—Except as provided in subsection (d)(8), if the Administrator". 3 (2) The table of contents in section 1(b) of the Federal Insecticide, Fungicide, and Rodenticide Act 6 (7 U.S.C. prec. 121) is amended by striking the item 7 relating to section 24(c) and inserting the following: "(c) Additional uses. "(1) In general. "(2) Disapproval. "(3) Consistency with Federal Food, Drug, and Cosmetic "(4) Suspension of authority to register pesticides. "(d) Registration of Canadian pesticides by States. "(1) Definitions. "(2) Authority to register Canadian pesticides. "(3) Requirements for registration sought by person. "(4) State requirements for registration. "(5) Disapproval of registration by Administrator. "(6) Labeling of Canadian pesticides. "(7) Revocation. "(8) Suspension of State authority to register Canadian pesticides. "(9) Limits on liability. "(10) Disclosure of information by Administrator to the "(11) Provision of information by registrants of comparable domestic pesticides. "(12) Penalty for disclosure by State. "(13) Data compensation. "(14) Formulation changes.". 8 (c) Effective Date.—This section and the amendments made by this section take effect 180 days after the
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date of enactment of this Act.